CHECKLIST OF REQUIREMENTS FOR DRUG DISTRIBUTOR / MANUFACTURER; MEDICAL DEVICE; COSMETIC ESTABLISHMENTS

General Requirements: (ALL FORMS TO BE ACCOMPLISHED IN TRIPlicate)

- Information as to activity of the establishment
- Notarized Accomplished Petition Form / Joint Affidavit of Undertaking
- Photocopy of Business Name Registration with DTI (if single proprietor); with SEC (if corporation/partnership) and Articles of Incorporation
- ID Picture of the Owner / Gen. Manager and Pharmacist (size 2 x 2)
- Photocopy of Pharmacist’s Registration Board Certificate, PRC-ID, PTR and Certificate of Attendance to any Sponsored/Accredited Seminar on Licensing of Establishment
- Notarized valid Contract of Lease of the space/building occupied, if the applicant does not own it.
- Location Plan / Site (size, location, immediate environment, type of building)
- List of Products to be manufactured/distributed in Generic and Brand Names (therapeutic classification dosage & strength)
- Number of personnel (technical and non-technical), the academic qualification and relevant experience.
- Duties and responsibilities of the Pharmacist and other Technical Personnel
- Notarized Financial Statement of Cosmetic and Medical Device Establishment
- If importing raw materials and/or finished products add C 1 requirements
- Distribution Record Book duly registered with BFAD

Reference Books:
1. USP/NF (latest edition)
2. R.A. 3720; R.A. 5921
3. Remington’s Pharmaceutical Sciences (latest ed.)
4. Goodman & Gilman Pharmaceutical Basis of Therapeutics
5. British Pharmacopoeia
6. PNDF

Additional Requirements:

A. MANUFACTURER
   - Information Sheet
   - Floor Plan with complete dimensions and proper identification of areas with description
   - Organizational structure
   - List of Manufacturing / Quality Control equipment and facilities (per AO 56)

B. TRADER
   - Notarized valid Contract of Agreement with the manufacturer with stipulation that both Manufacturer / Repacker and Trader are jointly responsible for product quality.

C. DISTRIBUTOR
   1. IMPORTER:
      - Foreign Agency Agreement
      - Certificate of Status of Manufacturer (cGMP Certificate) issued by a Govt. Health Agency
   2. EXPORTER:
      - A valid Contract of Agreement with BFAD Licensed Manufacturer/Supplier
   3. WHOLESALER:
      - A valid Contract of Agreement with BFAD Licensed Manufacturer/Trader and/or Distributor
      - Certificate of Product Registration (CPRs)
      - Copy of License to Operate of Suppliers

Changes in Circumstances:
   - Official letter re: Change of Address / Owner / Business Name and/or etc.
   - Surrender original / old License to Operate and COC/CTR
   - Deed of Sale/Transfer of Rights in case of change of ownership
   - Notarized Affidavit of Pharmacist in case of change of pharmacist
IN THE MATTER OF PETITION OF:

TO OPEN A DRUG / COSMETIC ESTABLISHMENT, MORE PARTICULARLY AS A:

_____ Manufacturer : ( ) Drug ( ) Cosmetic ( ) Medical Device
_____ Trader : ( ) Drug ( ) Cosmetic ( ) Medical Device
_____ Drug Distributor : ( ) Importer ( ) Exporter ( ) Wholesaler
_____ Cosmetic Distributor : ( ) Importer ( ) Exporter ( ) Wholesaler
_____ Medical Device Distributor : ( ) Importer ( ) Exporter ( ) Wholesaler

P E T I T I O N

COMES NOW the undersigned petitioner unto the Bureau of Food and Drugs, Department of Health, Alabang, City of Muntinlupa, Metro Manila, respectfully alleges;

FIRST – That the petitioner is of legal age, married/single, Filipino citizen and residing at ____________________________________________________________;

SECOND – That the petitioner desires to open a Drug / Cosmetic establishment, more particularly, a ___________________________ to be located at ________________________________ and shall be known as __________________________________ with Tel.No. __________________;

THIRD – That said establishment shall be open for business from ______ A.M. to ______ P.M. and shall be under the personal and immediate supervision of _____________________________________, a duly registered pharmacist with Certificate of Registration No. ___________________________ issued on ____________________________;

FOURTH – That __________________________________ is the owner of said establishment with the postal address at __________________________________________________________________;

FIFTH – That the amount of capital invested for said establishment P ______________________;

SIXTH – That the petitioner hereby agrees to change the business name of the establishment in the event that there is a similar or same name registered with the Bureau of Food and Drugs or if it rules later that it is misleading.

WHEREFORE, the petitioner respectfully prays that she/he be granted License to Operate a drug / cosmetic / medical device establishment after inspection thereof and after compliance with the Bureau of Food and Drugs’ requirements, rules and regulations.

Davao City, Philippines, __________________________, 20____.

The undersigned, as owner of the establishment, hereby declares under oath that he conforms to the declaration of the petitioner pharmacist.

Respectfully submitted:

Owner: ___________________________________ ______________________________________
Signature over Printed Name       Signature over Printed Name of Pharmacist

Address: ___________________________________ Address:
Residence Certificate No._________________________ Residence Certificate No. ______________________
Issued on: ____________________________ at ____________________________
Telephone / Cellphone No.: ____________________________ Telephone / Cellphone No.: ____________________________
SUBSCRIBED AND SWORN to before me this __________ day of ____________, 20 ___.
Affiant exhibited to me his/her Residence Certificate(s), the date of which are indicated below his/her
Respective name(s) on page hereof.

__________________________________
Notary Public

Doc. No. ______________
Page No. ______________
Book No. ______________
Series of ______________

INSTRUCTIONS

1. For single proprietorship, attach CERTIFICATE OF BUSINESS NAME REGISTRATION from
the Department of Trade and Industry (DTI). For corporation, partnership, or other juridical
person, attach CERTIFICATE OF REGISTRATION with the Securities and Exchange
Commission (SEC), together with a copy of Articles of Incorporation and By-Laws. If the
applicant is an alien, the petition must be accompanied by an authenticated copy of the
CERTIFICATE OF ALIEN REGISTRATION.

2. All drugs and cosmetic products, prior to their introduction into the domestic commerce, must
first be registered with BFAD.

3. Application must be accompanied by BFAD-LSS Form No. 6 re: Clearance of Name, for
purpose of misbranding provisions of R.A. 3720.

4. For other requirements, consult BFAD License Inspector.
I. Name of Proprietor: ____________________________________________________

II. Name of Establishment: _______________________________________________

III. Address of Pharmaceutical, Drug Manufacturing Lab.: ____________________

_____________________________________________________________________

IV. List of Product to be Manufactured: ____________________________

V. Floor plan of Laboratory: (Diagram including the adjacent grounds indicating location of windows and doors, their dimensions and their directional exposures. Floor and lower half of the wall and sink location. Mention essential laboratory basic facilities necessary for the manufacture (e.g. vacuum, compressed air, electrical connection, steam & gas)

VI. List of equipment and apparatuses:

a. General equipment and apparatuses:
   1. ________________________________________________________________
   2. ________________________________________________________________
   3. ________________________________________________________________
   4. ________________________________________________________________
   5. ________________________________________________________________
   6. ________________________________________________________________
   7. ________________________________________________________________
   8. ________________________________________________________________
   9. ________________________________________________________________
  10. _________________________________________________________________

b. Specific production equipment especially concerned in the products to be manufactured:
   1. ________________________________________________________________
   2. ________________________________________________________________
   3. ________________________________________________________________
   4. ________________________________________________________________
   5. ________________________________________________________________
   6. ________________________________________________________________
   7. ________________________________________________________________
   8. ________________________________________________________________
   9. ________________________________________________________________
  10. _________________________________________________________________

VII. Source of Raw Materials to be used:

   a. Local : __________________________________________________________
   b. Imported : _______________________________________________________
   c. Import finished product for rebottling only : __________________________

VIII. Number of Personnel:

   a.) Pharmacist(s) ____________________ d.) Technicians __________________
   b.) Chemist(s) ______________________ e.) Helpers & Janitors _______________
   c.) Bacteriologist(s) ________________ f.) Others __________________________

IX. Capital Invested: ______________________________

X. Estimated output of each product per day or month: _______________________

    I, declare that the foregoing statement is true, correct and complete to the best of my Knowledge and belief.

_____________________________________________________________________

Name & Signature of Authorized Person          Title       Date
JOINT AFFIDAVIT OF UNDERTAKING

I, ____________________________________________________, Pharmacist-In-Charge with
(Family Name, First Name, Middle Name)

PRC Registration Number : __________________
Issued on : _______________________________
PTR No. : _______________________________
of legal age, single/married and a resident of _______________________________________
(Permanent Home Address)

and OWNER of
____________________________________________________________________________
(Name of Company)
located at  ___________________________________________________________________
(Address of Company)
of legal age, and a resident of  _______________________________________________
after having been sworn in accordance with law, hereby declares:

1. That we are fully aware of the provisions of Pharmacy Law, the Foods, Drugs, Devices
and Cosmetics Acts, the Generics Act of 1988 and that we are aware of the specific
requirements that the operation of __________________ shall be under the
IMMEDIATE AND PERSONAL SUPERVISION of the Pharmacist-in-Charge with
business hours being from __________ AM to __________ PM;

2. That we agree to change the business name if there is already as validly registered name
similar to business name;

3. That we shall display the approved License to Operate in a conspicuous place of my
establishment;

4. That we shall notify BFAD in case of any change(s) in the circumstances of our
application for a license to operate, including but not limited to change(s) of location,
change of pharmacist-in-charge and change in drug products;

5. And that the Pharmacist-in-charge, will not be in any way connected with any other drug
or similar establishment/outlet;

WITNESS HEREOF, I hereunto affix our signatures this ________ day of
___________________, 200___.

_____________________________   _______________________________
Owner       Pharmacist

Res. Cert. No. ___________________  Res. Cert. No. ___________________
Issued On ______________________  Issued On ______________________
At  ____________________________  At  ____________________________

SUBSCRIBED AND SWORN to me this _______ day of __________________,
200___, at __________________________.

________________________________
NOTARY PUBLIC
Until December 31, 20____